

Notice of Allowability	Application No.	Applicant(s)	
	09/485,005	WANKER ET AL.	
	Examiner	Art Unit	
	GAILENE R. GABEL	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment filed 2/26/09 and Interview Summary on 6/5/09.
2. ☒ The allowed claim(s) is/are Claims 1-5, 8-20, and 27-41; renumbered as claims 1-10, 12-16, 20-22, 11, 17-19, and 23-33, respectively.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☒ to Paper No./Mail Date 12/04/2001.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>2/26/09</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>6/5/09</u> . 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|---|---|

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

6/5/09

EXAMINER'S AMENDMENT

1. An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on June 5, 2009, Ms. MaryDilys Anderson requested an extension of time for 1 MONTH and authorized the Director to charge Deposit Account No. 23/2325 the required fee for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2. The application has been amended as follows:

In claim 1, line 3 after the preamble, the following has been inserted:

--(a) treating a sample suspected of comprising amyloid-like fibrils or protein aggregates by adding detergent or urea to solubilize the sample;--

Thereafter in the next line of claim 1, [step] "(a)" has been deleted and [step] --(b)-- has been inserted therefor.

In claim 1, step b) line 2 after "amyloid-like fibrils or", "amyloid" has been deleted; and then after "protein aggregates, the comma "," has been deleted.

In claim 1, step b) line 3 "material of a" has been deleted and --the-- has been inserted therefor; and then after "sample", "suspected to comprise said amyloid-like

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fibrils or aggregates which has been previously treated with detergent or urea to solubilize the sample” has been deleted.

In claim 1 at line 11, [step] “(b)” has been deleted and --(c)-- has been inserted therefor.

In claim 1, step c) line 1 after “detecting”, “whether” has been deleted; and then after “amyloid-like fibrils or”, --protein-- has been inserted; and then after “aggregates”, -that-- has been inserted.

In claim 8, lines 1-2 after “prior to step”, “(b)” has been deleted and --(c)-- has been inserted therefor; and then after “the following step is carried out:”, “(b’)” has been deleted and --(c’)-- has been inserted therefor.

In claim 9, line 3 after “filter with”, “material of” has been deleted; and then after “the sample in step”, “(a)” has been deleted and --(b)-- has been inserted therefor.

In claim 10, line 2, “(b)” has been deleted and --(c)-- has been inserted therefor; and then after “or peptide or polypeptide,” “preferably” has been deleted.

In claim 11, line 2, “(b)” has been deleted and --(c)-- has been inserted therefor.

In claim 12, line 1 after “The method of claim 1 wherein”, “said material of” has been deleted.

In claim 13, step a), line 2 after “amyloid-like fibrils or”, “amyloid” has been deleted.

In claim 13, step a), line 3 after “aggregates with”, “material of” has been deleted.

In claim 13, step b) line 1 after “detecting”, “whether” has been deleted; and then after “amyloid-like fibrils or”, --protein-- has been inserted; and then after “aggregates”, -that-- has been inserted.

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In claim 13, step b) line 2 after “on said filter wherein”, “said material of” has been deleted.

In claim 18, line 2 after “spotting or pipetting”, “said material of” has been deleted.

In claim 39, line 3, “material of” has been deleted.

In claim 40, line 2, after “or peptide or polypeptide,” “preferably” has been deleted.

3. The following is an examiner’s statement of reasons for allowance: the prior art of record fails to teach or fairly suggest treating a sample suspected of containing amyloid-like fibrils or amyloid-like protein aggregates with detergent or urea to specifically solubilize the sample so as to remove and separate the portions of the amyloid-like fibrils or amyloid-like protein aggregates that are soluble to detergent or urea; and then subjecting the solubilized sample to filtration using cellulose acetate or nitrocellulose having a pore size that retains the detergent or urea insoluble portions of the amyloid-like fibrils or amyloid-like protein aggregates so as to physically capture and detect the detergent or urea insoluble amyloid-like fibrils or amyloid-like protein aggregates present in the sample that are retained in the cellulose acetate or nitrocellulose filter.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAIENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

June 5, 2009